Pacific Northwest National Laboratory

PNNL Institutional Review Board

Human Subjects Research Program

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Assurances:
FWA4696 - IRB0285
HHS MPA-1221
DOE.MPA.PNNL-2005

The Review Process

This section of the web site is designed to explain the IRB process, in particular those items that must be taken into consideration as protocols undergo review (see **IRB Worksheet** (PDF)). Basic to the entire process is an assessment of the risks and benefits that might accrue to individual subjects or to society as a whole to ensure that risks are minimized and benefits are maximized to the greatest extent possible.

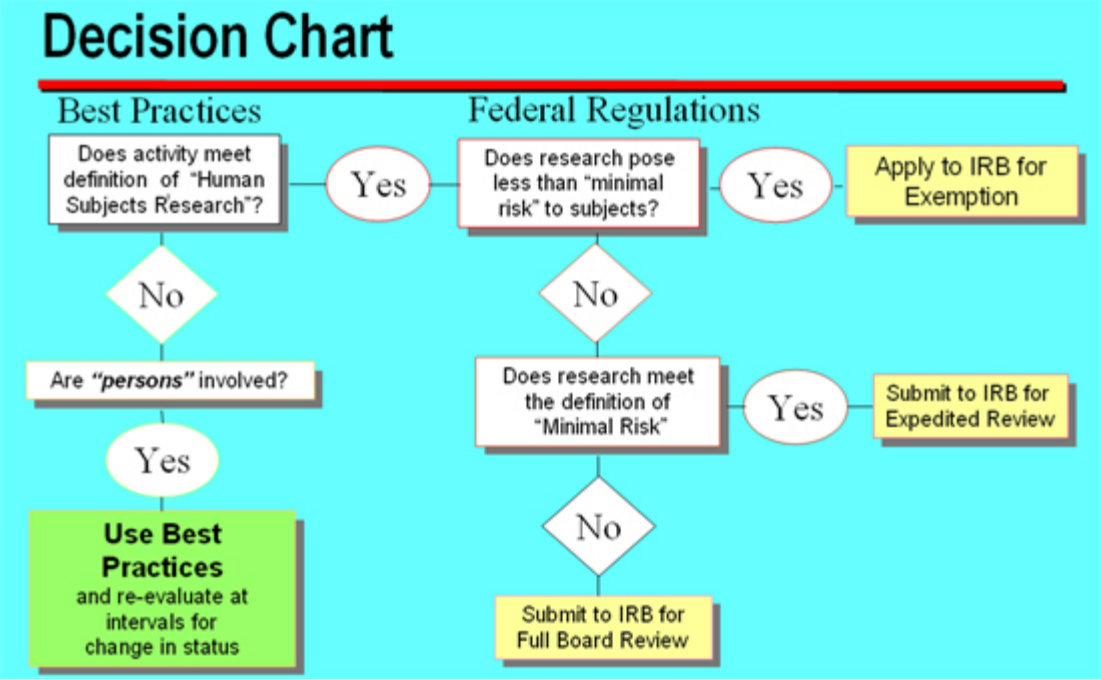
Researchers are responsible for notifying the IRB whenever proposed activities include the use of human subjects. Formal IRB review may be delayed until notification of funding but researchers should be aware that some clients, in particular, The National Institute of Health, require documentation of IRB approval before they will perform scientific review of a proposal and often only provides a few days advance notice. Full Board review may take up to 3-4 weeks to complete, so where there is a strong indication of funding, we recommend that IRB review be completed as early as possible.

Experienced researchers consult the IRB during proposal development to ensure that their plan for involving human subjects is appropriate, is properly managed, and meets the criteria for approval. By doing so, they avoid future pitfalls and are able to demonstrate to their management and their clients that the procedures, safeguards and costs associated with the use of human subjects have been fully considered and incorporated into the work plan. The IRB highly recommends this approach.

It's important to remember that human subjects research may not begin or continue without (1) IRB approval and (2) documentation that key research staff have completed human subjects training.

The PNNL **Human Subjects Review Process** (PDF) provides an overview of the steps required to complete IRB review.

The following "**Decision Chart**" was developed by staff in the Information Sciences and Engineering Department to visually describe the process researchers and IRBs must go through to determine if research is subject to Human Subjects Regulations or simply requires that Best Practices be implemented. The IRB is responsible for making the final determinations.



Levels of Review

There are three types of review based, for the most part, on the level of risk to subjects:

- **Exempt Review**: To qualify for exempt review, research must meet **the Federal criteria for exemption** (PDF). When those criteria can be met, researchers may submit a "Request for Exemption" to the IRB for consideration.

- **Expedited Review**: Activities that meet the definition of "*minimal risk*" may qualify for **expedited review**. Expedited review may be conducted by the IRB Administrative Team or by members of the Team, individually, if determined appropriate by the IRB.

- **Full Board Review**: Activities that do not meet the definition of "*minimal risk*," or are, for some other reason, believed by the IRB or researcher to require a more intense review, are reviewed by the entire Board.

Examples of Activities that Do Not Qualify for IRB Review, but Require Best Practices When "Persons" are Involved:

- Internal surveys such as PNNL's Quality of Life Survey, or external surveys to assess local and state business awareness of PNNL capabilities (when the results do not lead to generalizable scientific knowledge).

- Taking photographs/video or audio-taping if the activities are not conducted for the purpose of research.

- Occupational health studies, when they contain no element of research.

When in doubt as to whether or not your research requires review, call the IRB Program Manager, **Sherry Davis** at (509) 375-3610.

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Reviewed: October 6, 2004

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